UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

COUNTY OF HENDERSON, TEXAS	§	
Plaintiff,	§	
v.	§	
PURDUE PHARMA, L.P.;	§	
PURDUE PHARMA INC.;	§	
THE PURDUE FREDERICK COMPANY;	§	
PURDUE PHARMACEUTICALS L.P.;	§	
CEPHALON, INC.;	§	
TEVA PHARMACEUTICAL INDUSTRIES, LTD;	§	
TEVA PHARMACEUTICALS USA, INC.;	§	**Civil Action No.:6:19-cv-00309**
JANSSEN PHARMACEUTICALS, INC.;	§	**COMPLAINT AND JURY DEMAND**
JOHNSON & JOHNSON;	§	
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
ENDO HEALTH SOLUTIONS, INC.;	§	
ENDO PHARMACEUTICALS, INC.;	§	
ABBOTT LABORATORIES;	§	
KNOLL PHARMACEUTICAL COMPANY;	§	
ALLERGAN PLC f/k/a ACTAVIS PLC;	§	
ALLERGAN FINANCE LLC f/k/a ACTAVIS, INC**.** f/k/a WATSON PHARMACEUTICALS, INC.;	§	

ALLERGAN SALES LLC;	§
ALLERGAN USA INC.;	§
WATSON LABORATORIES, INC.;	§
WATSON PHARMA, INC.;	§
ACTAVIS LLC;	§
ACTAVIS PHARMA, INC., f/k/a ACTAVIS, INC.;	§
MCKESSON CORPORATION;	§
MCKESSON MEDICAL SURGICAL INC.;	§
CARDINAL HEALTH, INC.;	§
CARDINAL HEALTH 110 LLC;	§
CARDINAL HEALTH 200 LLC;	§
CARDINAL HEALTH 414 LLC;	§
AMERISOURCE BERGEN DRUG CORPORATION;	§
MALLINCKRODT PLC;	§
MALLINCKRODT, LLC;	§
COVIDIEN PLC;	§
MALLINCKRODT BRAND PHARMACEUTICALS;	§
SPECGX, LLC;	§
ABBVIE, INC.;	§
KNOLL PHARMACEUTICAL COMPANY;	§
CVS HEALTH;	§
WALGREENS BOOTS ALLIANCE, INC., a/k/a WALGREEN CO.;	§
WAL-MART STORES, INC.;	§
RITE AID CORPORATION;	§
THE KROGER COMPANY;	§
AND DOES 1 THROUGH 100 INCLUSIVE.	§
	§

***Defendants*.**

PLAINTIFF'S ORIGINAL PETITION

Plaintiff, the County of Henderson, Texas (the "County"), by and through the undersigned attorneys, against Defendants, Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Cephalon, Inc., Teva Pharmaceutical Industries, LTD, Teva Pharmaceuticals USA,

Inc., Teva Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Abbott Laboratories, Knoll Pharmaceutical Company, Allergan PLC, f/k/a Actavis PLC, Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Allergan Sales LLC, Allergan USA Inc., Watson Laboratories, Inc., Watson Pharma, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Actavis, Inc., McKesson Corporation, McKesson Medical Surgical Inc., Cardinal Health, Inc., Cardinal Health 110 LLC, Cardinal Health 200 LLC, Cardinal Health 414 LLC, AmerisourceBergen Drug Corporation, Mallinckrodt, PLC, Mallinckrodt, LLC, Covidien PLC, Mallinckrodt Brand Pharmaceuticals, SpecGX LLC, Abbvie, Inc., Knoll Pharmaceutical Company, CVS Health, Walgreens Boot Alliance, Inc. a/k/a Walgreen Co., Wal-Mart Stores, Inc., Rite Aid Corporation, the Kroger Company, and Does 1 – 100, alleges as follows:

VENUE AND JURISDICTION

1. Venue is proper in the United States District Court for the Eastern District of Texas because all or a substantial part of the events or omissions giving rise to this claim occurred in the Eastern District of Texas. *See* 28 U.S.C. § 1391.

2. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1331.

3. This Court has specific jurisdiction over all Defendants as their activities were directed toward Texas and injuries complained of resulted from their activities. Each Defendant has a substantial connection with Texas and the requisite minimum contacts with Texas necessary to constitutionally permit the Court to exercise jurisdiction.

PARTIES

4. Plaintiff brings this action for and on behalf of the County, which provides a wide range of services on behalf of its residents, including, but not limited to, services for families and children, public health, public assistance, law enforcement, and social services, as well as medical and prescription benefits that the County provides to its employees and retirees.

CORPORATE DEFENDANTS

CORPORATE DEFENDANTS

5. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut. PURDUE PHARMACEUTICALS L.P. is licensed by the Food & Drug Safety Licensing Group of the Texas Department of State Health Services ("DSHS") as a manufacturer and/or distributor of prescription drugs in Texas (collectively "Purdue").

6. Purdue manufactures, promotes, sells, and distributes opioids nationally and in Henderson County, including among them OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

7. Purdue is engaging in business in the State of Texas and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808.

8. CEPHALON, INC. ("Cephalon.") is a Delaware corporation with its principal place

of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon. TEVA PHARMACEUTICAL INDUSTRIES, LTD ("Teva, Ltd.") is an Israeli company with its corporate headquarters in Petah Tikva, Israel. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Teva, Ltd., Teva USA, and Cephalon, Inc. (collectively "Cephalon") work together closely to market and sell Cephalon products in the State of Texas. Teva conducts all sales and marketing activities for Cephalon in the State of Texas through Teva USA and has done so since it's October 2011 acquisition of Cephalon.

9. Cephalon manufactures, promotes, sells, and/or distributes opioids nationally and in Henderson County, including Actiq and Fentor, for which Cephalon is identified as the drug sponsor and Teva USA is identified as the distributor.

10. Cephalon is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Cephalon can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

11. JANSSEN PHARMACEUTICALS, INC. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly-owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a

Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief: J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (collectively "Janssen").

12. Janssen manufactures, promotes, sells, and/or distributes opioids nationally and in Henderson County, including Duragesic, Nucynta and Nucynta ER. These opioid drugs are sold both directly by Janssen and by third party drug distributors. Janssen is engaging in business in the State of Texas and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201.

13. ENDO HEALTH SOLUTIONS, INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC. is a wholly-owned subsidiary of ENDO HEALTH SOLUTIONS INC. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (collectively "Endo.").

14. Endo manufactures, promotes, sells, and/or distributes opioids nationally and in Henderson County, including Opana and Opana ER. Opana ER is reported to have been prescribed up to 50,000 times per day. However, June 8, 2017, the U.S. Food and Drug Administration requested that Endo remove Opana ER from the market based on FDA's concern that the benefits of the drug may no longer outweigh its risks. Endo is engaging in business in the State of Texas and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201.

15. ABBOTT LABORATORIES is an Illinois corporation with its principal place of business in Abbott Park, Illinois. KNOLL PHARMACEUTICAL COMPANY is a wholly-owned

subsidiary of Abbott Laboratories and is a New Jersey corporation with its principal place of business in Parsippany, New Jersey (collectively "Abbott").

16. Abbott currently and/or historically manufactures, promotes, sells, and/or distributes opioids nationally and in Henderson County, including Vicoprofen and Dilaudid. Abbott Laboratories can be served by serving its registered agent as follows: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

17. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to ALLERGAN FINANCE, LLC as of October 2013. Allergan Finance, LLC is a Nevada Corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, The Corporation Trust Company of Nevada, 701 S. Carson St., Suite 200, Carson City, NV 89701. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), and may be served through its registered agent for service of process, Corporate Creations Network, Inc., 8275 South Eastern Ave., #200, Las Vegas, NV 89123. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC., and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and may be served

through its registered agent for service of process, Corporate Creations Network, Inc., 3411 Silverside Rd., Tatnall Building, Suite 104, Wilmington, DE 19810. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in Texas. Upon information and belief, Allergan plc exercised control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit (collectively "Actavis.").

18. Actavis manufactures, promotes, sells, and/or distributes opioids nationally and in Henderson County, including generic Oxycontin (oxycodone hydrochloride) and Dilaudid (hydromorphone hydrochloride). ALLERGAN SALES is identified as the sponsor and/or entity responsible for the manufacture and/or distribution of the opioid medication Fiorinal with codeine (FDA NDA # 019429). Actavis acquired the rights to another opioid, Kadian (morphine sulfate, NDA # 020616), from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

19. Actavis has elected to do business in the State of Texas under a license as a domestic drug manufacturer and/or distributor. The entities that are licensed by DSHS to conduct business in Texas as domestic licensees are: Allergan Sales LLA. 8301 Mars Dr. Waco, Texas 76712 Allergan USA Inc., 800 Waters Ridge Dr. 100, Lewisville, Texas 75057.

20. Plaintiff alleges that Allergan Sales LLC and Allergan USA Inc. are domiciled in the State of Texas and are proper parties who may be sued under their assumed or common names for enforcing for or against it a substantive right TEX. R. CIV. P. 28. Allergan Sales LLC and Allergan USA Inc. may be served at the above addresses.

21. The foregoing defendants are referenced in this petition as the "Manufacturing Defendants."

22. MCKESSON CORPORATION ("McKesson") is a Delaware corporation with its

principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Henderson County. The drugs distributed by McKesson include powerful, addictive opioids, such as oxycodone and hydrocodone.

23. McKesson is engaging in business in the State of Texas and may be served through its registered agent for service of process, CSC – Lawyers Incorporating Service, 211 E. 7th Street, Suite 620, Austin, TX 78701.

24. McKesson has elected to do business in Texas under a license as a domestic drug manufacturer and/or distributor. There are three "McKesson" entities that are licensed by DSHS to conduct business in Texas as domestic licensees.

25. Plaintiff alleges that McKesson Corporation and MCKESSON MEDICAL-SURGICAL INC. are domiciled in the State of Texas and are proper parties who may be sued under their assumed common name for enforcing for or against it a substantive right TEX. R. CIV. P. 28. McKesson Corporation and McKesson Medical-Surgical Inc. may be served at the above addresses.

26. CARDINAL HEALTH, INC. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Henderson County. The drugs distributed by Cardinal include powerful, addictive opioids, such as oxycodone and hydrocodone.

27. Cardinal is engaging in business in the State of Texas and may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons, Suite 125, Columbus, OH 43219.

28. Cardinal has elected to do business in Texas under a license as a domestic drug

manufacturer and/or distributor. There are nine "Cardinal" entities that are licensed by DSHS to conduct business in Texas as domestic licensees.

29. Plaintiff alleges that CARDINAL HEALTH 110 LLC, CARDINAL HEALTH 200 LLC AND CARDINAL HEALTH 414 LLC are domiciled in the State of Texas and are proper parties who may be sued under their assumed or common name for enforcing for or against it a substantive right Tex. R. Civ. P. Cardinal Health 110 LLC, Cardinal Health 200 LLC and Cardinal Health 414 LLC, may be served at the above addresses.

30. AMERISOURCE BERGEN DRUG CORPORATION ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Henderson County. The drugs distributed by Amerisource include powerful, addictive opioids, such as oxycodone and hydrocodone.

31. Amerisource is engaging in business in the State of Texas and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

32. Amerisource has elected to do business in Texas under a license as a domestic drug manufacturer and/or distributor. There are two Amerisource entities that are licensed by DSHS to conduct business in Texas as domestic licensees, including: Amerisource Bergen Drug Corporation 12727 W. Airport Blvd. Sugarland, Texas 77478.

33. Plaintiff alleges that Amerisource Bergen Drug Corporation is domiciled in the State of Texas and is a proper party who may be sued under its assumed or common name for enforcing for or against it a substantive right. TEX. R. CIV. P. 28. Amerisource Bergen Drug Corporation may be served at the above address.

34. MALLINCKRODT PLC ("Mallinckrodt") is an Irish public limited company with its corporate headquarters in Staines-Upon-Thames, Surrey, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC, was a wholly-owned subsidiary of COVIDIEN PLC. MALLINCKRODT BRAND PHARMACEUTICALS is a Delaware Corporation which is wholly owned by Mallinckrodt plc. Defendant SPECGX, LLC, is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt, LLC Mallinckrodt, plc, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals, and SpecGx, LLC, are referred to as "Mallinckrodt." Mallinckrodt distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Henderson County. The drugs distributed by Mallinckrodt include powerful, addictive opioids, such as oxycodone and hydrocodone.

35. ABBVIE, INC. ("Abbvie") is a Delaware corporation with its principal place of business in North Chicago, Illinois, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. KNOLL PHARMACEUTICAL COMPANY ("Knoll") has been a wholly-owned subsidiary of Abbvie from January 1, 2013. Knoll is a New Jersey corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, CT Corporation System, 350 N St. Paul Street, Dallas, Texas 75201.

36. Knoll irresponsibly marketed narcotics, such as Vicodin, through toys and

souvenirs and did so to boost the sales of opioids. Taking advantage of the fact that Vicodin was not regulated as a Schedule II controlled substance for many years, and the fact physicians and consumers did not fully appreciate the highly addictive nature of Vicodin, Knoll advertised Vicodin with tag lines such as "The Highest Potency Pain Relief You Can Still Phone In." This tag line came as part and parcel of souvenirs like a "Vicodin" fanny pack and water bottle, both bearing the name of Vicodin, the opioid Knoll was promoting. This irresponsible marketing of a narcotic drug caused doctors and patients to believe Vicodin was safer than it really was, to the detriment of people in Henderson County. Abbvie began manufacturing, developing, promoting, marketing, and selling the opioid drug, Vicodin, in the U.S. and its opioid business impacts Henderson County. On information and belief, it continues to do so at the time of filing this pleading.

37. CVS HEALTH ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. CVS is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, CVS can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079. During all relevant times, CVS Health has sold and continues to sell prescription opioids in and in close proximity to Henderson County.

38. WALGREENS BOOTS ALLIANCE, INC., a/k/a WALGREEN CO. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 211 E. 7th Street, Suite 620, Austin, Texas 78701. At all relevant times, Walgreens has sold and continues to sell prescription opioids in close proximity to Henderson County.

39. WAL-MART STORES, INC. ("Wal-Mart") is a Delaware corporation with its

principal place of business in Arkansas and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. At all relevant times, Wal-Mart has sold and continues to sell prescription opioids at locations in and in close proximity to Henderson County.

40. Defendant RITE AID CORPORATION ("Rite Aid") is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid, through its various DEA registrant subsidiaries and affiliated entities, distributed prescription opioids throughout the United States, including in the County. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States and in the County.

41. Defendant THE KROGER COMPANY ("Kroger") is an Ohio corporation with its principal office located in Cincinnati, Ohio. At all times relevant to this Complaint, Kroger, through its various DEA registrant subsidiaries and affiliated entities, distributed prescription opioids throughout the United States, including in the County. Kroger may be served through its resident agent, Corporate Service Company DBA CSC – Lawyers Inc., 211 E. 7th Street, Suite 620, Austin, Texas 78701.

42. The foregoing defendants are referenced in this petition as the "Distributor Defendants."

43. CVS, Walgreens, Walmart, Rite Aid, and Kroger are additionally collectively referenced in this petition as the "Pharmacy Defendants."

FACTUAL ALLEGATIONS

44. Defendants, in an attempt to sell more pharmaceutical drugs, changed doctors' views regarding opioids through deceptive marketing schemes. Each Defendant used direct

marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use.

45. Generally accepted standards of medical practice prior to 1990 dictated that opioids should be used only for short-term acute pain, which included pain relating to recovery from surgery or for break-through cancer pain or palliative (end-of-life) care. Prescriptions for opioids to treat chronic pain was discouraged or even prohibited because there was a lack of evidence that opioids improved patients' ability to overcome pain and to function. Instead the evidence demonstrated that patients developed tolerance to opioids over time, which increased the risk of addiction and other side effects.

46. Upon information and belief, Defendants spread their false and deceptive statements by:

(i) marketing their branded opioids directly to doctors treating patients residing in the County and the County patients themselves; and

(ii) deploying so-called unbiased and independent third parties to the County.

47. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

48. Several Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, implying that the drug would

provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Pursuant to a settlement agreement, Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Texas.

49. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices– and small-group speaker programs. Defendants devoted massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors, including $108 million by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis. This amount is twice as much as Defendants spent on detailing in 2000.

50. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically-accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

51. Upon information and belief, Defendants employed the same marketing plans, strategies, and messages in and around the County as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

52. Upon information and belief, Defendants also deceptively marketed opioids in and around the County through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for treating chronic pain.

53. Unbranded advertising also avoided regulatory scrutiny because Defendants did not have to submit it to the FDA, and therefore it was not reviewed by the FDA.

54. Defendants' deceptive unbranded marketing often contradicted their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**

"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

55. Defendants spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported using opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

56. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

57. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

58. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage using opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants

were able to direct and exert control over each of these activities through their KOLs.

59. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

60. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

61. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Endo, Janssen, and Purdue (among others), and was a paid consultant to Purdue.

62. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

63. Dr. Portenoy also made frequent media appearances promoting opioids. He appeared on *Good Morning America* in 2010 to discuss using opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Texas and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very

assured that that person is not going to become addicted."[1]

64. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[2] These lectures falsely claimed that less than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[3] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."[4]

65. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake County, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster authored numerous CMEs sponsored by Endo and Purdue while he was receiving significant funding from Defendants.

66. In 2011, Dr. Webster presented a program via webinar sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended using risk screening tools, such as urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths," which was available to and was, upon information and belief, intended to reach doctors treating the County's residents.

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[1] Good Morning America television broadcast, ABC News (Aug. 30, 2010).
[2] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.
[3] *Id.*
[4] *Id.*

67. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[5]

68. Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations ("Front Groups") to promote opioids for treating chronic pain. Under Defendants' direction and control, the Front Groups generated:

(i) treatment guidelines;

(ii) unbranded materials; and

(iii) programs that favored chronic opioid therapy.

They also assisted Defendants by responding to:

(i) negative articles, by advocating against regulatory changes that would limit prescribing opioids in accordance with the scientific evidence; and

(ii) by conducting outreach to vulnerable patient populations targeted by Defendants.

69. The Front Groups were funded by the Defendants and depended on the

[5] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

Defendants in some cases for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure these Groups would generate only the messages Defendants wanted to distribute. Even so, the Front Groups held themselves out as independent and as serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

70. Defendants Endo, Janssen, and Purdue utilized many Front Groups. Some of the Front Groups include the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

71. The American Pain Foundation ("APF") received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next at $1.7 million.

72. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

73. APF issued education guides for patients, reporters, and policymakers that touted

the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were, upon information and belief, intended to reach patients and consumers in the County.

74. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

75. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

76. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids 37 out of roughly 40 at one conference alone. AAPM's presidents have

included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[6]

77. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

78. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed there was a low risk that patients would become addicted to opioids. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was taken down from AAPM's website only after a doctor complained, though it still lingers on the internet elsewhere.

79. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend using opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Endo, and Purdue.

80. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper,

[6] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because he was concerned the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, were, upon information and belief, disseminated in and around the County during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

81. Upon information and belief, to convince doctors treating residents in the County and the County patients that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and effective. Knowing they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by, or were contrary to, the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them and continue to spread them today.

82. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because

most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, does not pose special risks; and (4) abuse-deterrent opioids both prevent overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

83. Defendants falsely claimed the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and failed to disclose the greater risk of addiction with prolonged use of opioids. For example:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 claiming opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond;

b. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online;

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them;"

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com;

e. Janssen reviewed, edited, approved, and distributed a patient education

guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain;"

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated;"

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction []." This publication is still available online; and

h. Upon information and belief, detailers for Purdue, Endo, and Janssen in and around the County minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for opioid abuse with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

84. These claims contradict longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[7] The guideline points out that "[o]pioid pain medication use presents serious risks, including…opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[8]

85. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA discussed the risks related to opioid use and that IR opioids are associated with "persistent abuse, addiction, overdose mortality, and risk of NOWS

[7] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016).

[8] *Id.*

[neonatal opioid withdrawal syndrome]."[9]

86. According to the FDA, because of the risks associated with long-term opioid use, including "the serious risk of addiction, abuse, misuse, overdose, and death,"[10] opioids should be "reserved for pain severe enough to require opioid treatment and for which alternative treatment options (e.g., non-opioid analgesics or opioid combination products, as appropriate) are inadequate or not tolerated."[11]

87. The warnings on Defendants' own FDA-approved drug labels caution that opioids "exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death"[12] and that addiction "can occur in patients appropriately prescribed"[13] opioids.

88. Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, and Purdue – and claimed that pseudoaddiction is substantiated by scientific evidence. For example:

a. Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition continues to teach that pseudoaddiction is real;

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that

[9] *FDA Announcement of Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, Federal Drug Administration (Mar. 22, 2016).
[10] *Id.*
[11] *Id.*
[12] *See, e.g.*, OxyContin label and insert at *OxyContin.com.*
[13] *Id.*

may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management;"

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials;

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated;" and

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

89. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment…are unlikely to experience pain relief with longer-term use,"[14] and that physicians should "reassess [] pain and function within 1 month"[15] in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids"[16] because

[14] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

[15] *Id.*

[16] *Id.*

the patient is "not receiving a clear benefit."[17]

90. Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting opioid therapy for chronic pain. For example:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts;

b. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" and

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

91. The 2016 CDC Guideline confirms these representations are false. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts – widely believed by doctors to detect and deter outcomes related to addiction and overdose.[18] As a result,

[17] *Id.*

[18] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

the Guideline recognizes that doctors should not overestimate the risk screening tools for classifying patients as high or low risk for opioid addiction because they are insufficient to rule out the risks of long-term opioid therapy.[19]

92. To downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem thereby failing to disclose the increased difficulty of stopping opioids after long-term use.

93. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."

94. Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

95. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be limited to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,"[20] because "physical dependence on opioids is

[19] *See id.*

[20] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

an expected physiologic response in patients exposed to opioids for more than a few days."[21] The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence"[22] and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal"[23] and pausing and restarting tapers depending on the patient's response.

96. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced, or opioids are discontinued."[24]

97. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond;

b. Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide

[21] *Id.*

[22] *Id.*

[23] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

[24] *Id.*

stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online;

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain;"

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief;"

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages;

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will;

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online;

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages; and

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

98. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for

chronic pain are not established"[25] while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[26]

99. More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[27] Similarly, there is an "increased risk for opioid use disorder, respiratory depression, and death at higher dosages."[28] That is why the CDC advises doctors to avoid increasing dosages above 90 morphine milligram equivalents per day.

100. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged that available data suggested that increasing the opioid dosage likewise increased certain adverse events. For example, the FDA noted that studies suggest a positive association between high-dose opioid use and overdoses.

101. Finally, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse.

102. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter addiction and overdose. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant in a way that suggested it was more difficult to misuse the product. This claim was false.

103. The FDA warned in a 2013 letter that there was no evidence Endo's design would

[25] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

provide a reduction in oral, intranasal or intravenous use.[29] Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

104. In a 2016, settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was designed to be or is crush resistant. The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER.

105. Similarly, the 2016 CDC Guideline states that no studies support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,"[30] noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[31]

106. These numerous, long-standing misrepresentations of the risks of long-term opioid use were spread by Defendants and successfully convinced doctors and patients to discount those risks.

107. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants had to persuade them that there was a significant benefit to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[32]

108. In fact, the CDC found no evidence showing "a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year

[29] *See FDA Statement: Original Opana ER Relisting Determination* (May 10, 2013).

[30] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

[31] *Id.*

[32] *Id.*

later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[33] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use.

109. In 2013, the FDA stated that it was unaware of any studies demonstrating the safety and efficacy of opioids for long-term use.[34] Despite this lack of studies, Defendants falsely and misleadingly touted the benefits of long-term opioid use and suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today. For example:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives;

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function;

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved

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[33] *Id.*

[34] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

patients' function. The book remains for sale online;

f. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012;

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast;

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube;

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health- related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today; and

k. Purdue's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

110. These claims find no support in the scientific literature. Most recently, the 2016 CDC Guideline, approved by the FDA, concluded, "There is no good evidence that opioids

improve pain or function with long-term use"[35] and "complete relief of pain is unlikely."[36] (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."[37]

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy;"[38] and

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[39]

111. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[40] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

112. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience…results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or

[35] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*

enjoyment of life."[41]

113. Defendants also falsely emphasized or exaggerated the risks of competing products like nonsteroidal anti-inflammatory drugs ("NSAIDs") so that doctors and patients would look to opioids first for treating chronic pain. Once again, Defendants' misrepresentations contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence.

114. Consequently, the FDA changed the labels for extended release and long acting opioids in 2013 and immediate release opioids in 2016 to state that opioids should be used only as a last resort where alternative treatments like non-opioid drugs are inadequate. And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

115. In addition, Purdue misleadingly promoted OxyContin as unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action.

116. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. The reason is that OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. Although the patient experiences a powerful initial response, there is little or no pain relief at the end of the dosing period because less medicine is released.

117. This phenomenon is known as "end of dose" failure, and the FDA found in 2008

[41] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

that a substantial number of chronic pain patients taking OxyContin experience it.

118. This "end of dose" failure not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

119. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors in and around the County that OxyContin lasts a full 12 hours.

120. Defendants herein participated in illicit and unlawful prescribing of its drugs. For example, Purdue did not report illegal prescribing of OxyContin until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets. In doing so, Purdue protected its own profits at the expense of public health and safety.

121. The State of New York found that Endo failed to require sales representatives to report signs of addiction, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

122. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S. and, upon information and belief, in and around the County. For example, Defendants focused their deceptive marketing on

primary care doctors, who were more likely to treat chronic pain patients and prescribe opioids but were less likely to be educated about treating pain and the risks and benefits of opioids.

123. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

124. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

125. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

126. Not only did the FDA and other regulators warn Defendants, but Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use, including the suffering from addiction, overdoses, and death in alarming numbers in patients using opioids.

127. More recently, the FDA and CDC have issued pronouncements based on the

medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described herein in New York.

128. Specifically, three current and former executives from Purdue plead guilty in 2007 to criminal charges that they misled regulators, doctors, and patients about OxyContin's risk of addiction.[42] In pleading guilty to misbranding charges, Purdue admitted it had fraudulently marketed OxyContin as a drug less prone to addiction and as having fewer side effects than other opioids.[43] In reality, unlike other opioids, OxyContin contained pure oxycodone without any other ingredients, which made it a powerful narcotic despite its time-release design that Purdue touted as ameliorating its addictive potential.[44]

129. Moreover, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs.

130. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not.

131. Thus, Defendants successfully concealed from the medical community and patients' facts sufficient to arouse suspicion of the claims the County now asserts. The County did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

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[42] *See Barry* Meier, "In Guilty Plea, OxyContin Maker to Pay $600 Million," (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.
[43] *See id.*
[44] *See id.*

132. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies reveal that many doctors and patients are unaware of or do not understand the risks or benefits of opioids. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[45]

133. While Defendants may claim the federal government authorized the amount of annual prescription opioids sold, they know in truth that several Defendants have successfully used their organized money and influence to render the federal government's enforcement agency, the Drug Enforcement Administration, virtually powerless to interrupt the over-supply of prescription opioid drugs.

134. Upon information and belief, Defendants' deceptive marketing scheme caused and continues to cause doctors in and around the County to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have been able to over prescribe opioids or become embroiled in pill mills that negatively impacted residents of the County.

135. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

136. Defendants' deceptive marketing has caused and continues to cause the

[45] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction.

prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending tripled to $288 million.

137. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and the County.

138. Scientific evidence demonstrates a strong correlation between opioid prescriptions and becoming addicted to opioids. In a 2016 report, the CDC explained that prescribing opioids has quadrupled since 1999, which has resulted in a parallel increase in opioid overdoses.[46] Indeed, there has been a two-third increase in overdose deaths from using opioids since 2000.[47] For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic."[48]

139. Due to the increase in opioid overdoses, first responders such as police officers, have been and will continue to be in the position to assist people experiencing opioid-related overdoses. In 2016, "over 1,200 law enforcement departments nationwide carried naloxone in an

[46] CDC. National Vital Statistics System, Mortality. CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/; Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

[47] *National Vital Statistics System*, Mortality file and appearing *Center for Disease Control and Prevention* Morbidity and Mortality Weekly Report, January 1, 2006 / 64(50); 1378-82, Increases in Drug and Opioid Deaths – United States, 2000-2014.

[48] *CDC Guideline for Prescribing Opioids for Chronic Pain, supra; see also* Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

effort to prevent opioid-related deaths."[49]

140. Upon information and belief, Defendants' deceptive marketing scheme has also detrimentally impacted children in the County. Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household.

141. Upon information and belief, Defendants' conduct has adversely affected the County's child protection agencies in the number of children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for counties like the County.

142. Upon information and belief, opioid addiction is a significant reason that the County residents seek treatment for substance dependence. A significant number of admissions or drug addiction were associated with a primary diagnosis of opiate addiction or dependence.

143. Upon information and belief, Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed the County communities. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids to which people are addicted come, directly or indirectly, through doctors' prescriptions.[50]

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[49] *Id. citing* http://www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/.

[50] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

144. Law enforcement agencies have increasingly associated prescription drug addiction with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

145. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has more than doubled in the past decade among adults aged 18 to 25 years.[51] Moreover, heroin-related overdoses in the United States has more than quadrupled since 2010.[52]

146. The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid addiction and dependence was estimated at $25 billion, the cost of criminal justice was estimated at $5.1 billion, and the cost of lost workplace productivity was estimated at $25.6 billion.

147. Consequently, prescription opioid addiction and overdose have an enormous impact on the health and safety of individuals, as well as communities at large, because the consequences of this epidemic reach far beyond the addicted individual.

148. Upon information and belief, some of the repercussions for residents of the County include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration, which result in instability in communities often already in

[51] Centers for Disease Control and Prevention. Vital Signs: Today's Heroin Epidemic – More People at Risk, Multiple Drugs Abused. (https://www.cdc.gov/vitalsigns/heroin/index.html). MMWR 2015.
[52] https://www.cdc.gov/vitalsigns/heroin/index.html

economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers, and law enforcement.

149. Defendants knew and should have known about these harms that their deceptive marketing has caused and continues to cause and will cause in the future. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding.

150. Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Defendants not only knew but intended that their misrepresentations would persuade doctors to prescribe and encourage patients to use their opioids for chronic pain.

151. Defendants' actions are neither permitted nor excused by the fact that their drug labels may have allowed, or did not exclude, the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by, and guidance from, the FDA based on the medical evidence and their own labels.

152. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also hijacked what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

153. Upon information and belief, Defendants' actions and omissions were each a

cause-in-fact of the County's past and future damages. Upon information and belief, Defendants' wrongful conduct caused injuries to the County in the past, continues to cause injuries to the County, and will continue to cause injuries to the County in the future. Future damages include, but are not limited to, additional resources for counseling and medication assisted treatment of addicts, medical treatment for overdoses, life skills training for adolescents, increased law enforcement, and additional resources to treat the psychological effects of opioids and the underlying conditions that make people susceptible to opioid addiction.

154. While using opioids has taken a toll on the County and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

155. Manufacturer Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths-all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing

medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

156. Notwithstanding this knowledge, at all times relevant to this Complaint, Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct.

157. Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Purdue, Endo, Teva, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information. Defendants also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

158. Manufacturer Defendants thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the County now asserts. The County did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

159. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to release the DEA-reported ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart

diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to meet their obligations to report suspicious orders and prevent diversion.

160. Texas law specifically requires that dispensers like Distributor Defendants monitor opioid prescription orders and to refuse to fill prescription orders for opioids that are without valid medical purpose. In spite of the existence of an opioid epidemic in Henderson County, and the fact that Distributor Defendants knew or should have known of that epidemic, Distributor Defendants continued to fill each opioid prescription order in Henderson County, including those that were without valid medical purpose--thus stoking the epidemic.

161. In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

162. DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

163. Specifically, DEA has identified several types of "unresolvable red flags" which, when presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include:

164. A prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; Multiple prescriptions presented by the same practitioner to patients form the same address, prescribing the same controlled substances in each presented prescription; A high volume of patients presenting prescriptions and paying with cash; A

prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

165. When a pharmacist identifies any such red flags of diversion, the pharmacist must not fill the prescription. Filling a prescription without resolving such red flags is a violation of a pharmacist's legal duty and corresponding responsibility not to fill a prescription outside the usual course of practice and for other than a legitimate medical purpose. Under Texas law, "a pharmacist may not dispense a prescription drug if the pharmacist knows or should know that the prescription was issued without a valid practitioner-patient relationship." See Texas Occ. Code, § 562.056(a).

166. Mirroring the CFR, Texas law requires that, before dispensing a prescription, a pharmacist must use her own sound professional judgment and discretion to determine that the prescription is a valid prescription." Texas Occ. Code, § 562.056(a). Just as in the CFR, "[t]o be a valid prescription, a prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner 's professional practice." Texas Occ. Code, § 562.056(a-1). Further, "[t]he responsibility for the proper prescribing and dispensing of prescription drugs is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Texas Occ. Code, § 562.056(a-1).

167. This responsibility to ensure prescriptions are filled only for a valid medical purpose rests with the pharmacy, but, "[a] pharmacy shall ensure that its agents and employees, before dispensing a prescription, determine in the exercise of sound professional judgment that the prescription is a valid prescription." Texas Occ. Code, § 562.112(a). See also Texas Admin. Code § 291.34(b)(1)(D). The Texas Administrative Code imparts further duties upon pharmacists acting in the course of professional practice, including:

> Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or

diversion of prescription drugs, and records for such drugs. Texas Admin. Code § 291.33(2)(a).

A pharmacist shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed. If the pharmacist questions the accuracy or authenticity of a prescription drug order, the pharmacist shall verify the order with the practitioner prior to dispensing. Texas Admin. Code § 291.29(a)

A pharmacist shall make every reasonable effort to ensure that any prescription drug order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a practitioner in the course of medical practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued without a valid pre-existing patient-practitioner relationship as defined by the Texas Medical Board in 22 Texas Administrative Code (TAC) §190.8 (relating to Violation Guidelines) or without a valid prescription drug order. Texas Admin. Code § 291.29(b).

If a pharmacist has reasons to suspect that a prescription was authorized solely based on the results of a questionnaire and/or in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid patient-practitioner relationship or in violation of the practitioner's standard of practice include:

(1) the number of prescriptions authorized on a daily basis by the practitioner;
(2) a disproportionate number of patients of the practitioner receive controlled substances;
(3) the manner in which the prescriptions are authorized by the practitioner or received by the pharmacy;
(4) the geographical distance between the practitioner and the patient or between the pharmacy and the patient;
(5) knowledge by the pharmacist that the prescription was issued solely based on answers to a questionnaire;
(6) knowledge by the pharmacist that the pharmacy he/she works for directly or indirectly participates in or is otherwise associated with an Internet site that markets prescription drugs to the public without requiring the patient to provide a valid prescription order from the patients practitioner; or
(7) knowledge by the pharmacist that the patient has exhibited doctor-shopping or pharmacy-shopping tendencies. Texas Admin. Code § 291.29(c).

A pharmacist shall ensure that prescription drug orders for the treatment of chronic

> pain have been issued in accordance with the guidelines set forth by the Texas Medical Board in 22 TAC §170.3 (relating to Guidelines), prior to dispensing or delivering such prescriptions. Texas Admin. Code § 291.29(d).
>
> A prescription drug order may not be dispensed or delivered if issued by a practitioner practicing at a pain management clinic that is not in compliance with the rules of the Texas Medical Board in 22 TAC §§195.1 - 195.4 (relating to Pain Management Clinics). A prescription drug order from a practitioner practicing at a certified pain management clinic is not automatically valid and does not negate a pharmacist's responsibility to determine that the prescription is valid and has been issued for a legitimate or appropriate medical purpose. Texas Admin. Code § 291.29(e).
>
> Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug unless the pharmacist complies with the requirements of §562.056 and §562.112 of the Act, and §291.29 of this title (relating to Professional Responsibility of Pharmacists). Texas Admin. Code § 291.34(b)(1)(B).

168. Inherently, a prescription presenting a red flag of diversion cannot be a valid prescription. Thus, a Texas pharmacy has a legal duty to identify red flags of diversion, and to refuse to fill any prescription presenting any such red flags. The Texas Board of Pharmacy has identified many categories of red flags in its history of binding Pharmacy Board orders and opinions. Additional types of suspicious orders and red flags include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible as compared to most written prescriptions; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time,

these attributes are not difficult to detect and should be easily recognizable by pharmacies.

169. Other signs of diversion can be observed through data that is gathered, consolidated, and analyzed directly by Pharmacy Defendants. That data allows national retail pharmacies to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies. The majority of pharmacies sell these records.

170. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted. Pharmacy Defendants obligations under Texas law inherently included obligations to prevent diversion, to identify evidence of prescription diversion, and to report such evidence to the Board of Pharmacy.

COUNT I
PUBLIC NUISANCE
(ALL DEFENDANTS)

171. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

172. Upon information and belief, Defendants knowingly encouraged doctors in and around the County to prescribe, and residents to use, highly-addictive opioids for chronic pain even though Defendants knew using opioids had a high risk of addiction and reduced quality of life.

173. Upon information and belief, by doing so, Defendants purposefully interfered

with the County's public health, public safety, public peace, public comfort, and public convenience.

174. Upon information and belief, Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health and safety of the County residents and/or unreasonably interferes with the peace and comfortable enjoyment of life in violation of Texas law.

175. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community – and the harm inflicted outweighs any offsetting benefit.

176. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused, and continues to cause, harm to the community including, but not limited to:

a. Upwards of 30% of all adults use opioids. These high rates of use have led to unnecessary opioid addiction, overdose, injuries, and deaths;

b. Children have been exposed to opioids prescribed to family members or others resulting in injury, addiction, and death. Upon information and belief, easy access to prescription opioids has made opioids a recreational drug of choice among the County teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure causing severe withdrawal symptoms and lasting developmental impacts;

c. Upon information and belief, residents of the County, who have never taken opioids, have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages, or other support from family members who have used, become addicted to, overdosed on, or been killed by opioids;

d. Upon information and belief, more broadly, opioid use and addiction have driven the County residents' health care costs higher;

e. Employers have lost the value of productive and healthy employees who have suffered from adverse consequences from opioid use;

f. Defendants' success in extending the market for opioids to new patients

and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them;

g. This demand has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process;

h. Upon information and belief, diverting opioids into secondary, criminal markets and increasing the number of individuals who are addicted to opioids has increased the demands on emergency services and law enforcement in the County;

i. All of Defendants' actions have caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes;

j. Upon information and belief, these harms have taxed the human, medical, public health, law enforcement, and financial resources of the County; and

k. Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is limited social utility to opioid use and any potential value is outweighed by the gravity of harm inflicted by Defendants' actions.

177. Defendants knew, or should have known, that promoting opioid use would create a public nuisance in the following ways:

a. Upon information and belief, Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of the County;

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;

c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs; and

d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences that the larger community would suffer as a result.

178. Upon information and belief, Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain thereby causing opioids to become widely available and used in the County.

179. Without Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid addiction would not have existed and could have been averted.

180. Upon information and belief, the health and safety of the citizens of the County, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to the County's citizens and residents.

181. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

182. Upon information and belief, Defendants' conduct has affected and continues to affect a considerable number of people within the County and is likely to continue to cause significant harm to patients who take opioids, their families, and the community at large.

183. Each Defendant created or assisted in creating the opioid epidemic, and each Defendant is jointly and severally liable for its abatement. Furthermore, each Defendant should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in the County.

COUNT II
COMMON LAW FRAUD
(ALL DEFENDANTS)

184. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

185. At all relevant and material times, Defendants expressly and/or impliedly warranted that opioids were safe, of merchantable quality, and fit for use.

186. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of opioids, and their intentional dissemination of promotional and marketing information about opioids for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with opioids.

187. At all times herein mentioned, Defendants, individually and acting through their employees and agents, and in concert with each other, fraudulently represented to physicians who Defendants knew would justifiably rely on Defendants' representations that opioids were safe and effective for treating chronic pain.

188. Upon information and belief, Defendants' false representations were fraudulently made, with the intent or purpose that healthcare providers and patients would justifiably rely upon them, leading to the prescription, administration, filling, purchasing, and consumption of opioids in the County.

189. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein include, but are not limited to:

a. Making false and misleading claims regarding the known risks of the addictive nature of opioids and suppressing, failing to disclose, and

mischaracterizing the addictive nature of opioids and in concomitant costs, such as overdoses, deaths, and heroin addiction;

b. Making false and misleading written and oral statements that opioids are more effective than traditional pain killers for chronic pain, or effective at all and/or omitting material information showing that opioids are no more effective than other non-addictive drugs for chronic pain;

c. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using opioids;

d. Making false and misleading claims downplaying the risk of addiction when using opioids and/or setting forth guidelines that would purportedly identify addictive behavior; and

e. Making false and misleading misrepresentations concerning the safety, efficacy and benefits of opioids without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

190. Defendants willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risk of opioids.

191. Defendants made these misrepresentations with the intent that the healthcare community and patients located wherever these opioid drugs were sold or consumed would rely upon them.

192. Defendants' misrepresentations were made with the intent of defrauding and deceiving the medical community and consumers to induce and encourage the sale of opioids.

193. Upon information and belief, Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers living in the County.

194. Defendants omitted, misrepresented, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of opioids, as well as the fact that the product was unreasonably dangerous.

195. Upon information and belief, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of opioids.

196. Upon information and belief, the treating medical community and consumers in the County did not know that Defendants' representations were false and/or misleading and justifiably relied on them.

197. Defendants had sole access to material facts concerning the dangers and unreasonable risks of opioids, which they intentionally concealed.

198. Upon information and belief, as a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which the medical community and consumers in the County reasonably relied, the County suffered actual and punitive damages.

COUNT III
NEGLIGENCE
(ALL DEFENDANTS)

199. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

200. Manufacturing Defendants have a duty to exercise reasonable care in marketing their opioids to physicians treating residents of the County and the County residents. Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

201. Manufacturing Defendants have used deceitful marketing ploys, KOLs, Front Groups, and other schemes to increase profits at the cost of public health causing an opioid

epidemic. Manufacturing Defendants have acted willfully, wantonly, and maliciously.

202. Likewise, Distributor Defendants have a duty to exercise ordinary care in distributing opioids. Distributor Defendants have breached their duty by failing to prevent or reduce the distribution of opioids, or to report the increase in the distribution and/or sale of opioids.

203. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids, or to report any increases in the sale of opioids, so that they could increase profits and receive rebates or kick-backs from Manufacturing Defendants. Distributor Defendants have acted willfully, wantonly, and maliciously.

204. Upon information and belief, as a proximate result, Manufacturing and Distributor Defendants and their agents have caused the County to incur excessive costs to treat the opioid epidemic in its county, including but not limited to increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

205. The County and its residents are therefore entitled to actual and punitive damages.

COUNT IV
GROSS NEGLIGENCE
(ALL DEFENDANTS)

206. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

207. Defendants' marketing scheme to optimize profits by misrepresenting and falsely touting opioids as the panacea to chronic pain was done intentionally.

208. Defendants' hiring of KOLs, Front Groups, and others to spread their fraudulent

message that opioids were useful and beneficial for chronic pain was grossly negligent and done with conscious indifference to the rights, safety, and welfare of others.

209. Each Defendant's actions and omissions as described herein, singularly or in combination with each other, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Each Defendant's actions and omissions described herein was done with actual and subjective awareness of the risk involved, but nevertheless demonstrated a conscious indifference to the rights, safety, and welfare of others.

210. Upon information and belief, at every stage, Defendants knew or should have known that their conduct would create an unreasonable risk of physical harm to others, including the County and its residents, and should be held liable in punitive and exemplary damages to the County.

COUNT V
UNJUST ENRICHMENT
(ALL DEFENDANTS)

211. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

212. Upon information and belief, as an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the County and its residents.

213. Upon information and belief, when the County and its residents purchased opioids, they expected that Defendants had provided necessary and accurate information regarding those risks. Instead, Defendants had misrepresented the material facts regarding the risks and benefits of opioids.

214. Upon information and belief, Defendants have been unjustly enriched at the expense of the County, and the County is therefore entitled to damages to be determined by the jury.

COUNT VI
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, et seq.
(ALL DEFENDANTS)

215. The County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

216. This claim is brought by the County against each Defendant for actual damages, treble damages, and equitable relief under and for violations of 18 U.S.C. § 1961, *et seq*.

217. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . ." 18 U.S.C. §1962(c).

218. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. §1962(c) and §1962(d).

219. Each Defendant herein participated in an Enterprise for purposes of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to sell and distribute drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons that obtain prescriptions for them.

220. To accomplish this purpose, the Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the sale and distribution of Defendants' opioids and popularize the misunderstanding that opioids are

effective for chronic pain and the risk of addiction is low ("the Scheme").

221. At all relevant times, each Defendant was aware of the Enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids.

222. In fact, Front Groups and KOLs received direct payments from Manufacturer Defendants in exchange their role in the Enterprise, and to advance the Enterprise's fraudulent marketing scheme whereas Distributor Defendants received kick-backs from Manufacturing Defendants if they reached particular monthly goals.

223. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) marketing, promotion, and advertisement of Defendants' opioid medicines; (2) advocacy at the state and federal level for change in the law governing the use, prescription, and distribution of Defendants' opioids; (3) issuing prescriptions and prescription guidelines for Defendants' opioids; and (4) issuing fees, bills, and statements demanding payment for prescriptions of Defendants' opioids.

224. The persons engaged in the Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by the Manufacturer Defendants.

225. The Enterprise functioned as a continuing unit for the purposes of executing the Scheme and when issues arose during the Scheme, each member of the Enterprise agreed to take actions to hide the Scheme and the existence of the Enterprise.

226. Each Defendant participated in the operation and management of the Enterprise by directing its affairs as described herein.

227. While Defendants participated in, and are members of, the Enterprise, they have an existence separate from the Enterprise, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

228. Defendants, singularly or in combination with another, orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives or detailers to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of legitimacy to the Manufacturer Defendants' Scheme; (6) retaining KOLs to promote the use of their opioid medicines and (7) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

229. To carry out, or attempt to carry out, the scheme to defraud, the members of the Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

230. Specifically, the members of the Enterprise have committed, conspired to commit,

and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§1341 and 1343), within the past ten years.

231. The Enterprise's predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

a. Mail Fraud: The members of the Enterprise violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via
U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

b. Wire Fraud: The members of the Enterprise violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

232. The mail and wire transmissions were made in furtherance of Defendants' Scheme and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for chronic pain; increase the prescription rate for opioids; and popularize the misunderstanding that the risk of addiction is low when using opioids.

233. The members of the Enterprise aided and abetted others in violating the law. To achieve their common goals, the members of the Enterprise hid from the County and its residents: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioids; and (3) the true nature of the relationship between the members of the Enterprise.

234. Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co-

conspirators agreed to conceal their fraudulent scheme.

235. The members of the Enterprise knew, and intended that, the County and its residents would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

236. The pattern of racketeering activity described herein is currently ongoing and open-ended and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

237. As a result of Defendants' racketeering activity, the County has been injured in their business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid related crimes and emergencies, and other public safety costs.

238. Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to the County and the public who are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. §1964(c).

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully prays:

a. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

b. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Texas law;

c. That Plaintiff recover all measures of damages, including punitive and exemplary damages, allowable under the law, and that judgment be

entered against Defendants in favor of Plaintiff;

d. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law; and

e. That Defendants be ordered to abate the public nuisance that they created in in violation of Texas common law.

REQUEST FOR JURY TRIAL

The County respectfully requests that all issues presented by its above Complaint be tried by a jury, with the exception of those issues that, by law, must be tried before the Court.

Date: July 10, 2019

Respectfully Submitted,

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